UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,642	08/19/2003	Dov Zipori	85189-4900	3766

28765 7590 04/20/2007

WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,642	ZIPORI ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005 and 19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachary Skelding, Group Art Unit 1644.

2. Applicant's amendments to the claims of December 20, 2005 and to the specification of July 19, 2006 have been entered.

3. Claims 10, 11, 16 and 17 have been amended.

   Claims 1-26 are pending.

   Claims 1-11, 13-15, 17 are under examination as they read on a polynucleotide comprising a transcript from a T cell receptor gene wherein the transcript comprises an intronic J sequences and an in frame methionine followed by a joining region followed by a constant region, wherein the elected species of polynucleotide is SEQ ID NO: 17.

   Claims 12, 16 and 18-26 have been withdrawn by the examiner as being drawn to a non-elected invention.

4. Applicant's provision of a Substitute Sequence listing on CRF and paper copy on May 3, 2006 is acknowledged. However, applicant has not properly amended the instant specification such that the Substitute Sequence listing is considered part of the specification. In particular, the paper copy of the Sequence Listing must be inserted into the application via amendment, just as any other amendment to the body of the specification would be carried out. It is not sufficient to simply indicate in a transmittal letter that the new paper copy of the specification should replace the original. See MPEP § 2429 and 37 C.F.R. § 1.121.

5. Upon reconsideration, the previous Restriction Requirement (mailed December 1, 2005) has been **VACATED**. The following new Restriction Requirement is set forth. The Examiner apologizes for any inconvenience to Applicant in this matter.

Restriction Requirement

6. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Groups 1-4. Claims 2-7 and 17, drawn to polynucleotides comprising a transcript from a T cell receptor gene wherein the transcript comprises an intronic Jβ sequence with an in frame methionine followed by a Jβ joining region followed by a Jβ constant region, ***encoding SEQ ID NOs: 1, 2, 17 and 38, respectively,*** classified in Class 536, subclass 23.4.

Groups 5-37, Claims 6 and 8-11, drawn to polynucleotides comprising a transcript from a T cell receptor gene wherein the transcript comprises an intronic Jα sequence with an in frame methionine followed by a Jα joining region followed by a Jα constant region, ***encoding SEQ ID NOs: 3-16 and 18-36, respectively,*** classified in Class 536, subclass 23.5.

Group 38, Claim 6, drawn to a polynucleotide comprising a transcript from a T cell receptor gene wherein the transcript comprises ***SEQ ID NO: 38***, followed by a J joining region followed by a J constant region, classified in Class 536, subclass 24.1.

Groups 39-74, Claim 19, drawn to synthetic peptides selected from ***SEQ ID NOs: 1-36***, classified in Class 530, subclass 300.

Groups 75-110, Claim 21, drawn to an antibody raised against synthetic peptides selected from ***SEQ ID NOs: 1-36***, classified in Class 530, subclass 387.1.

Group 111, Claims 22 and 23, drawn to a method for inducing mesenchymal cell growth comprising administering a polynucleotide according to claim 1, classified in Class 435, subclass 377.

Group 112, Claims 24 and 25, drawn to a method for suppressing mesenchymal cell growth comprising administering transected mesenchymal human cells comprising an antisense DNA according to claim 12, classified in Class 435, subclass 375.

Group 113, Claim 26, drawn to a method of marking mesenchymal cells comprising applying an antibody according to claim 20, classified in Class 435, subclass 7.1.

Group 114, Claim 12, drawn to an antisense polynucleotide of the polynucleotides of claim 1, classified in Class 536, subclass 24.3.

Group 115, Claim 16, drawn to a polypeptide encoded by the polynucleotides of claim 1, classified in Class 530, subclass 350.

7. **Claims 1, 13, 14 and 15 link the inventions of Groups 1-38.**

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 13, 14 and 15.

Claim 20 links the inventions of Groups 75-110.

The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 20.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.
Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. The inventions of Groups 1-4 and 5-37 are related but distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed have a materially different structure in that each represents a unique fusion of a particular intronic Jβ sequence with a particular Jβ joining region followed by a constant region or a particular intronic Jα sequence with a particular Jα joining region followed by a constant region, respectively. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

9. The inventions of Groups 39-74 are related but distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed have a materially different structure in that each represents a unique fusion of a particular intronic Jβ sequence with a particular Jβ joining region or a particular intronic Jα sequence with a particular Jα joining region. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

10. The inventions of Groups 75-110 are related but distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

    In the instant case, the inventions as claimed have a materially different structure in that each represents an antibody that bind to a unique fusion of a particular intronic Jβ sequence with a particular Jβ joining region or a particular intronic Jα sequence with a particular Jα joining region, and thus the antibodies that bind these sequences in turn have unique structures themselves. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

11. The inventions of Groups 1-4, 5-37, 38, 39-74, 75-110, 114 and 115 are different products. The products are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each product is patentably distinct, and searching of these Inventions would impose an undue burden.

12. The inventions of Groups 111-113 are drawn to different methods, which differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these inventions together.

13. The inventions of (Linking claims **1, 13, 14 and 15)** and **Group 111** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the invention of Group 111 can be practiced with a materially different product, such as platelet derived growth factor.

14. The inventions of Group 114 and Group 112 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the invention of Group 112 can be practiced with a materially different product, such as an antibody to platelet derived growth factor.

15. The inventions of Groups 75-110 and 113 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the invention of Group 113 can be practiced with a materially different product, such as an antibody against the mesenchymal cell surface protein SB-10.

16. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search.

    In addition, due to the size of the biological sequence databases, it takes significant time to search any given sequence. Moreover, it is additionally burdensome to search more than one structurally distinct biological sequence because patent applicants and prior art references often describe a biological sequences in different ways, and undue burden is required to correlate more than one biological sequence with the biological sequences as defined in the prior art. See the Official Gazette Notice of March 27, 2007 (Week #13).

    Thus it would be an undue burden for the examiner to search more than one structurally distinct invention. Accordingly, restriction for examination purposes as indicated is proper.

17. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

18. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

    The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

    Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

    If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
April 16, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC1600
4/16/07